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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,025	08/23/2005	Clifford Roy Elcombe	9404.18803	4760

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EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	**PAPER NUMBER**
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,025	ELCOMBE ET AL.	
	Examiner	Art Unit	
	Anna Pagonakis	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,3,6-8,10,11,13-15,17-23,25-27,29,31,32 and 34-37 is/are pending in the application.

4a) Of the above claim(s) 7, 8, 10, 14, 15, 17, 18-23, 25-27, 29, 31, 32, 34-37 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1, 3, 6, 11 and 13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 28 February 2005 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5 sheets.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The following is responsive to applicant's election and amendment received on June 7, 2007.

Claims 2, 4, 5, 9, 12, 16, 24, 28, 30, and 33 were previously cancelled. Applicant's Claims 7, 8, 10, 14, 15, 17, 18, 19, 20, 21, 22, 23, 25, 26, 27, 29, 31, 32, 34, 35, 36, and 37 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is Anna Pagonakis. Contact information is provided at the end of this Office Action.

Information Disclosure Statement

The information disclosure statements filed on April 7, 2005; June 20, 2005; and July 31 2006 have been received. Please see the attached initialed PTO-1449s. Documents with no year of publication provided were not considered.

Objections

The *title* of the disclosure is objected to because the current title is not descriptive of the presently claimed invention. Current invention only claims treatment for tumors whereas the title includes treatment of obesity, diabetes, hyperlipidaemia and inflammation. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6, 11 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. While the specification is enabled for treating breast cancer cells, colon tumor cells and prostate cancer cells with perfluorooctanoic acid or its salts and esters thereof, this does not reasonably provide enablement for other tumor/cancer types. The specification does not enable any person skilled in the art to which it pertains, or with which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This is a Scope of Enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the quantity of experimentation necessary,

(2) the amount or direction or guidance presented,

(3) the presence or absence of working examples,

(4) the nature of the invention,

(5) the state of the prior art,

(6) the relative skill of those in the art,

(7) the predictability or unpredictability of the art, and

(8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In *re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, .166 USPQ 18; 24 (1970). Keeping in mind, the Wands factors are relevant in the instant fact situation for the following reasons.

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art.

The invention relates to the treatment of tumors comprising administering perfluorooctanoic acid as recited in the instant claims. The relative skill of those in the art, is high, generally that of an M.D. or Ph.D. The factor is outweighed, however, by the unpredictable nature of the art. As

illustrative of the state of the art, the examiner cites Gura *et al.* (Science, 1997, 278: 1041-1042) and Johnson *et al.* (British J. of Cancer, 2001, 84(10): 1424-1431).

Gura *et al.* for evidentiary purposes, teaches that researchers face the problem of sifting through potential anticancer agents to find the ones promising enough to make human clinical trials worthwhile and further teach that since formal screening began in 155, many thousands of drugs have shown activity in either cell or animal models but that not only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second paragraphs). It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. Also, with regard to unpredictability, Johnson *et al.*, also cited for evidentiary purposes, teach that the *in vivo* activity of 39 different agents in a particular histology in a tumor model did not correlate to activity in the same human cancer. *In re Fisher*, 427 F.2d 833, 16 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

These articles plainly demonstrate that the art of treating tumors andcancer, particularly in humans, is extremely unpredictable, particularly in the case of a single compound being used to treat any and all tumors.

2. The breadth of the claims

All claims are extremely broad insofar as they disclose the general treatment of tumors with perfluorooctanoic acid.

3. The amount of direction or guidance provided and the presence or absence of working examples.

The specification provides no direction or guidance for determining the particular administration regimes (dosages, timing, administration routes, etc.) necessary to treat all of the various tumors claimed, particularly in humans. The working examples are limited to: 1) the antitumor effects of one compound, on a very limited number of tumors (*e.g.* breast derived, prostate derived and colon derived). No reasonably specific guidance is provided concerning useful therapeutic protocols for any other tumors.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate with the claims, the skilled artisan would not accept the assertion that the instantly claimed perfluorooctanoic acid or salts or esters thereof, could be predictably used as a treatment for all tumors as inferred in the claims and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of 35 USC § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 112

Claims 6 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the disclosure does not enable for being at risk of developing a tumor and therefore preventing the development of a tumor. Thus the phrase "risk of developing" is being interpreted as a prevention type invention.

These factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2nd 1400 (CAFC 1988) at 1404 wherein, citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the quantity of experimentation necessary,

(2) the amount or direction or guidance presented,

(3) the presence or absence of working examples,

(4) the nature of the invention,

(5) the state of the prior art,

(6) the relative skill of those in the art,

(7) the predictability or unpredictability of the art, and

(8) the breadth of the claims.

The factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In *re Fisher*, 57 CCPA

1099, 1108, 427 F.2d 833, 839, .166 USPQ 18; 24 (1970). Keeping in mind, the Wands factors are relevant in the instant fact situation for the following reasons.

In the instant case, (1) the amount of experimentation is large because, in order to prove prevention of a tumor virtually everyone would need to be tested since prevention means that no person receiving the claimed composition comprising perfluorooctanoic acid or a salt or ester thereof exhibits tumor formation. (2) Also, there is no guidance provided by the specification since no disclosure on how to determine whether administration of the claimed perfluorooctanoic acid medicament prevents tumors. Page 2 of the specification merely states that, "the patient may be a patient with or a at risk of excessive inflammation, for example with or at risk of arthritis, or a patient with or at risk of developing a tumour. The compound may reduce the development, growth or metastasis of a tumour." The alleged claim that the compound is effective in reducing the development, growth or metastasis of a tumour is unsubstantiated and unproven. Further, (3) the specification is totally devoid of any working examples of prevention of tumors using the claimed compound; As for the next Wands factor, (4) the quantity of experimentation necessary is high, because of the known unpredictability of the art (as discussed supra) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that the instantly claimed perfluorooctanoic acid or salt or ester thereof, could be predictably used as a prevention of tumors as inferred in the claims and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of 35 USC § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success. There is

prior art (5) that shows a correlation between perfluorooctanoic acid or a salt or ester thereof, and tumoral treatment. (6) The relative skill in the art is very high; (7) the predictability of the art is low with regard to the complete prevention of tumors. Finally, (8) the claims are extremely broad in the sense that they require the complete prevention of all types of tumors, any of which might be caused by a large number of factors.

Based on the analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 112

Claims 1, 3, 6, 11 and 13 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as perfluorooctanic acid, however, claims 1, 3, 6, 11 and 13 are directed to encompass esters of perfluorooctanoic acid, which only correspond in some undefined way to specifically instantly disclosed chemicals. Though the chemical structure of perfluorooctanoic acid is well known in the art, the esters of perfluorooctanoic acid do not meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 3, 4, 6, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Revici *et al.* (U.S. Patent No. 4,624,851; Issued Nov. 25, 1986; Filed March 22, 1985).

The instant claims recite a method of treatment, which comprises administering a compound comprising perfluorooctanoic acid or a salt or ester thereof.

Revici *et al.* disclose methods of treating neoplasms in lower animals and humans by administering an effective amount of perfluorooctanic acid (Claim 1). Neoplasms include cancers, sarcomas, lymphomas, leukemias as well as benign tumors (col 1, lines 44-46).

The practice of the invention taught in Revici et al. anticipates the instant claims. *The Oxford Dictionary of Biochemistry and Molecular Biology* defines "neoplasm" as any new and morbid formation of tissue; a tumour. According to wordnet.princeton.edu/perl/webwn "cancer" is any malignant growth or tumor caused by abnormal and uncontrolled cell division. Both of these terms are found in the specification and claims of the patent issued to Revici *et.al.* which claim that an effective amount of perfluorooctanoic acid can be administered for treating at least

some of the symptoms of cancer. Given the above definition of cancer, perfluorooctanoic acid would also be able to treat tumors, thus having the capability of behaving as an "anti-tumor agent." Therefore, the term "anti-tumor agent" used in the instant claims would fall directly on the claims of patent issued to Revici *et al.*

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pagonakis whose telephone number is 571-270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

Ardin H Marschel 8/8/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER